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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,331

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Ronald Yamamoto

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07/16/2008

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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT

PAPER NUMBER

3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,331	<b>Applicant(s)</b> YAMAMOTO ET AL.	
	<b>Examiner</b> JOHN F. RAMIREZ	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06/20/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 06/20/08 have been fully considered but they are not persuasive.

In regards with the 102(e) rejection. Applicant alleges that the reference used Mattrey does not disclose or suggest performing the introduction and/or excising using the percutaneous excision device under guidance by imaging the excision device. However, the examiner disagrees with applicant's assertions since Mattrey teaches in the abstract that the affected lymphatic structure can be removed surgically or by a suitable minimally invasive procedure, which implies the use of imaging guide surgery.

In regards to the 102(b) rejection. Applicant alleges that Goldenberg fails to disclose or suggest injecting a radiological contrast agent into the human breast and also fails to disclose or suggest identifying a sentinel lymph node using an imaging modality, as generally recited in independent claim 11.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., human breast) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to the argument that Goldenberg does not identify a sentinel lymph node. Goldenberg is detecting and treating cancer lesions or tumors in a patient using photoscanning or magnetic resonance imaging to detect the lesion (see col. 5, lines 45-

67; col. 7, lines 36-43), even though they are different types of cancer tumors, the development of cancer with respect to body tissue is likely the same. This is not patentable distinction.

Based on the above observations, the previous rejections using Mattrey and Goldenberg are maintained and repeated below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1-4 and 10** are rejected under 35 U.S.C.102 (e) as being anticipated by **Mattrey (US 6,444,192)**.

Mattrey discloses a method for removing a sentinel lymph node (see abstract), comprising the steps of: injecting a radiological contrast agent detectable by an imaging modality into an area of interest (see abstract, col. 5, lines 5-17); identifying a sentinel lymph node in at least one area of draining lymph nodes that receive lymphatic fluid from the area of interest by imaging the at least one area of draining lymph nodes utilizing the imaging modality (see abstract, col. 4, lines 30-67, col. 6, lines 33-43); introducing a percutaneous excision device into the at least one area of draining lymph nodes (col. 4, lines 53-65); and excising the identified sentinel lymph node in the at least one area of draining lymph nodes using the percutaneous excision device (col. 6, lines 33-44, col. 18, lines 48-57), where at least one of the introducing and the excising is performed under guidance by imaging at least portions of the identified sentinel lymph node and the excision device (see abstract, col. 4, lines 30-67, col. 5, lines 1-17), the imaging modality is selected from the group consisting of ultrasound imaging, computerized tomography (CT) scanning and magnetic resonance imaging (MRI) (see abstract, col. 6, lines 33-43).

**Claims 11-15, and 17** are rejected under 35 U.S.C. 102(b) as being anticipated by **Goldenberg (US 6,096,289)**.

Goldenberg discloses a method, comprising: injecting a radiological contrast agent and a second agent into an area of interest (see abstract, col. 5, lines 24-37); imaging at least one area of draining lymph nodes that receive lymphatic fluid from the area of interest utilizing a first imaging modality capable of detecting the radiological contrast agent (col. 5, lines 38-67); and excising, using a percutaneous excision device (col. 6, lines 41-62), the identified sentinel lymph node in the at least one area of draining lymph nodes (col. 5, lines 38-67), where at least one of the imaging and excising includes detection of the sentinel lymph node utilizing the second agent to confirm identification of the sentinel lymph node (col. 6, lines 1-40, col. 21, lines 4-38), detecting the radiological contrast agent by using one of the following imaging modalities: ultrasound imaging, computerized tomography (CT) scanning and magnetic resonance imaging (MRI) (see col. 5, lines 45-67). Goldenberg shows the use of radiological agent as well as blue dye, which can be used to identify the sentinel lymph node after the excision (col. 8, lines 23-34, col. 9, lines 5-15), using the radiological contrast agent to get an image of a lymph node (col. 5, lines 45-67); then uses the image to locate and excise the lymph node using a percutaneous excision device (col. 5, lines 45-67). The use of the blue dye is then used via visual inspection to confirm identification of the sentinel lymph node (col. 8, lines 34-63).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 5-9, 16 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mattrey (US 6,444,192) in view of Goldenberg (US 6,096,289)**. Mattrey discloses all the limitations except for the steps of injecting includes injecting the radiological contrast agent and at least one other agent to facilitate identification of the sentinel lymph node, in which the other agent is selected from the group consisting of a radioisotope and a blue dye, injecting further includes injection of a second agent in combination with the radiological contrast agent, further comprising the step of confirming the identification of the target sentinel lymph node after the excision using a detection modality different from the imaging modality, in which the second agent is a radioisotope and the detection modality is a gamma counter, in which the second agent is a blue dye and the detection modality is visual inspection. However, Goldenberg shows the use of radiological agent as well as blue dye, which can be used to identify the sentinel lymph node after the excision (col. 8, lines 23-34, col. 9, lines 5-15). The radioisotope can be detected using a gamma counter (col. 13, lines 17-38). Goldenberg uses the radiological contrast agent to get an image of a lymph node (col. 5, lines 45-67); then uses the image to locate and excise the lymph node using a percutaneous

excision device (col. 5, lines 45-67). The use of the blue dye is then used via visual inspection to confirm identification of the sentinel lymph node (col. 8, lines 34-63).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Mattrey with the above discussed enhancements would have been considered obvious because such modifications would have provided improved detection, therapy and/or biopsy procedure for lesions.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. R./  
Examiner, Art Unit 3737

/Brian L Casler/  
Supervisory Patent Examiner, Art Unit 3737